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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,429	10/20/1999	TOSHIHIRO SHIMIZU	2535USOP	7265
23115	7590	11/02/2005	EXAMINER	
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC INTELLECTUAL PROPERTY DEPARTMENT 475 HALF DAY ROAD SUITE 500 LINCOLNSHIRE, IL 60069			TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/403,429	<b>Applicant(s)</b> SHIMIZU ET AL.	
	<b>Examiner</b> Susan T. Tran	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 20,21,23-26,28,29,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20,21,23-26,28,29,31 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Receipt is acknowledged of applicant's Request for Continued Examination filed 08/11/05, Notice of Appeal filed 06/30/05, and Amendment filed 06/03/05.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/11/05 has been entered.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20, 21, 23-26, 28, 29, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al. US 6,365,184, in view of Khankari et al. US 6,024,981.

Depui teaches an oral dosage form comprising proton pump inhibitor including lansoprazole (column 3, lines 54-67, and column 6). The proton pump inhibitor is in the form of pellet comprising a core and a coating layer (column 8, lines 29-39; column 9, lines 7-67). The coated pellet are mixed with inactive tablet excipients including L-HPC and compressed into tablet having disintegration time between 15-30 seconds (column 13, lines 60-64; examples 2 and 5). Depui does not expressly teach the use of sugar in the solid mixture.

Khankari teaches a rapidly dissolving tablet comprising tablet excipients such as binder, and filler including sugar alcohol such as mannitol (see abstract; and column 9, lines 44-66). The amount of mannitol is disclosed in examples 4-8). The tablet disintegrated in the mouth in less than 45 seconds (column 11, lines 45-46; and column 15, lines 1-15). Thus, it would have been obvious to one of ordinary skill in the art to modify the oral dosage form of Depui using mannitol in view of the teaching of Khankari, because Khankari teaches the tablet dissolves rapidly in the mouth of the patient with a minimum of grit (abstract), because Khankari teaches using mannitol as a tablet excipient to achieve superior compressibility, hardness, and rapid dissolution within the mount (column 10, lines 34-47), and because Depui teaches using tablet excipients and

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other pharmaceutically acceptable additives in combination with the coated pellet to compress into tablet (column 13, lines 51-55).

It is noted that Depui does not teach the percent substitution of the hydroxypropoxyl group. However, it is the position of the examiner that the L-HPC of Depui would have a similar percent substitution of the hydroxypropoxyl group because Depui teaches the use of L-HPC to obtain a similar fast disintegrating tablet dosage having disintegration time falls within the claimed range (example 2).

Claims 20, 21, 23-26, 28, 29, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Depui et al., in view of Khankari et al. US 6,024,981 and Makino et al. EP 0 553 777 A2.

Depui and Khankari are relied upon for the reason stated above. Depui does not expressly teach the percent substitution of a hydroxypropoxyl group in the L-HPC.

Makino teaches a composition comprising granules having a core coated with spraying powder containing drug, L-HPC having a hydroxypropoxyl group of about 4-20%, and sucrose (column 1, lines 55-68, and column 3, lines 45-56). The drug can be selected from the group including benzimidazole (column 2, line 18). Makino also teaches the granules can be further coated with Eudragit® (enteric) (column 4, lines 15-29). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation select L-HPC having a content of the hydroxypropoxyl group from about 4 in view of the teaching of Makino with the expectation of providing a faster disintegrating dosage form, because the references teach the desirability to obtain a

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rapidly disintegrate tablet having superior compressibility, hardness, and pleasant organoleptic sensation in the mouth of the patient.

### ***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shimizu et al., and Phillips are cited as of interest for the teachings of effervescent table comprising lansoprazole.

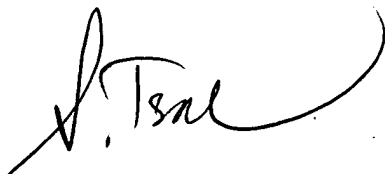
### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'S. Tran', with a large, sweeping flourish extending from the end of the signature.

S. Tran  
Patent Examiner  
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